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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | |
|-------------------------------|-------------|----------------------|---------------------|-----------------|--|
| 10/766,366 | 01/28/2004 | Pauline Pan | A0000367-03-EJF | 2888 | |
| 7590 06/27/2006 | | | EXAMINER | | |
| Darryl C. Little | e, Esq. | ROBERTS, LEZAH | | | |
| Pfizer Inc. 201 Tabor Road | | | ART UNIT | PAPER NUMBER | |
| Morris Plains, NJ 07950 | | | 1614 | | |

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application | n No. | Applicant(s) | | | | | |
|--|---|---|---|---|--------|--|--|--|--|
| Office Action Summary | | 10/766,366 | 3 | PAN ET AL. | | | | | |
| | | Examiner | | Art Unit | | | | | |
| | | Lezah W. F | Roberts | 1614 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | | |
| A SHOWHIC - Exter after - If NO - Failu Any I | ORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CF SIX (6) MONTHS from the mailing date of this communication period for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by steply received by the Office later than three months after the need patent term adjustment. See 37 CFR 1.704(b). | G DATE OF THI R 1.136(a). In no even to the control of the control of the control of the control | S COMMUNICATION ont, however, may a reply be time expire SIX (6) MONTHS from cation to become ABANDONEI | l. tely filed the mailing date of this coorsists U.S.C. § 133). | | | | | |
| Status | | | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on <u>G</u> | 3 April 2006. | | | | | | | |
| 2a) <u></u> □ | This action is FINAL . 2b) This action is non-final. | | | | | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | | | |
| Dispositi | on of Claims | | | | | | | | |
| 5)□ 6)⊠ 7)⊠ | Claim(s) 1-19 and 21-32 is/are pending in 4a) Of the above claim(s) 28-30 is/are with Claim(s) is/are allowed. Claim(s) 1-19, 21-27 and 31-32 is/are rejected to. Claim(s) 7 is/are objected to. Claim(s) are subject to restriction and subject to restri | drawn from cons | | | | | | | |
| Applicati | on Papers | | | | | | | | |
| 9) 10) | The specification is objected to by the Exar The drawing(s) filed on is/are: a) Applicant may not request that any objection to Replacement drawing sheet(s) including the co The oath or declaration is objected to by the | accepted or b)[the drawing(s) be arrection is require | e held in abeyance. Seed of the drawing(s) is obj | e 37 CFR 1.85(a). jected to. See 37 C | | | | | |
| Priority (| ınder 35 U.S.C. § 119 | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | | |
| 2) Notic | et(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948 mation Disclosure Statement(s) (PTO-1449 or PTO/SI | | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F | ate | O-152) | | | | |
| Paper No(s)/Mail Date 17 Jun 2004. | | | | | | | | | |

DETAILED ACTION

Response to Arguments

Claims 28-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 3, 2006.

Applicant's elections with traverse of Invention I and species hinokitiol in the reply filed on April 3, 2006 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden for the Examiner to examine all of the oral disease treatments of the present application under the same search. This is not found persuasive because the invention does not necessarily have to be used for oral care. The essential oils listed may be used in medications not necessarily used for oral care as disclosed by the method claims. In regards to the species, one cannot determine that a search for one species will produce results for all species encompassed by the claims without an extensive search.

The requirement is still deemed proper and is therefore made FINAL.

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Information Disclosure Statement

The information disclosure statement filed June 17, 2004 fails to comply with 37

CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document;

each non-patent literature publication or that portion which caused it to be listed; and all

other information or that portion which caused it to be listed. It has been placed in the

application file, but the information referred to therein has not been considered.

Claims

Claim Objections

Claim 7 is objected to because of the following informalities: the term "eucalptol"

should read "eucalyptol". Appropriate correction is required.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United

States.

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1) Claims 1-7, 14-19, 21, 23-25, 27 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lion Corp (JP 07-187973).

Lion Corp teaches liquid oral compositions comprising hinokitiol and other essential oils. The compositions are used for mouthwashes but may also be used for water toothbrushing and mouth deodorant. Hinokitiol may be incorporated into the compositions at levels ranging from 0.00005 to 0.1%, encompassing claims 3-5. Other components of the compositions include enzymes, fluorides, chlorhexidine salts, epsilon-aminocaroic acid and glycyrrhizin salts. The compositions also comprise other perfume articles such as anethole, eugenol, methyl salicylate, linalool, menthol and limonene. Menthol comprises 0.005 to 1% of the compositions (paragraph 0023), encompassing claims 17-19. Water is present from 50 to 95% (paragraph 0025), which is an oral carrier encompassing the instant claims. Ethanol comprises less than 3% of the composition, encompassing claims 23-25. Methyl salicylate was incorporated into a non-hinokitiol comprising example at 0.05%. It can be concluded methyl salicylate may be incorporated into compositions comprising hinokitiol in this amount, encompassing claims 14-16. The reference anticipates the claims insofar as it teaches compositions comprising hinokitiol, an essential oil and an oral carrier.

2) Claims 1-10, 14-19, 21, 23-25, 27 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugano et al. (JP 07-187977).

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Sugano et al. teach oral compositions comprising hinokitol. Hinokitiol may be incorporated into the compositions at concentrations ranging from 0.0001 to 0.1 %. The compositions comprise essential oils such as anethole, eugenol, methyl salicylate, linalool, menthol and limonene (paragraph 0017). Thyme oil may also be used in the compositions, in which thymol is one of its components and makes up about 49% of the oil. The thyme oil was incorporated into one of the compositions in conjunction with hinokitiol at a concentration of 0.05% (0.0245 % thymol), encompassing claims 8-10._ Ethanol is also in the compositions comprising about 3.5% in one example. Water was disclosed in all examples. The reference anticipates the claims insofar as it teaches compositions comprising hinokitiol, an essential oil and an oral carrier.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-19, 21-27 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp (JP 07187973A) in view of Fand et al. (US 3,164,524).

The primary reference, Lion Corp is discussed above and teaches oral compositions comprising hinokitiol and other essential oils such as menthol. The reference teaches other essential oils may be used in the compositions. The reference differs from the instant claims insofar as it does not teach specifically teach thymol and eucalyptol, and the specific weight percent for methyl salicylate.

The secondary reference, Fand et al., teaches oral antiseptic compositions comprising menthol, thymol, eucalyptol and methyl salicylate. The compositions with this combination of the essential oils have good antiseptic properties. Menthol is incorporated into the compositions from about 20 to about 60 mg, methyl salicylate from about 5 to about 100 mg, thymol from about 50 to about 100 mg and eucalyptol from

about 5 to 150 mg, encompassing claims 22 and 26. The reference differs from the instant claims insofar as it does not teach the using hinokitiol in the compositions.

It would have been obvious to one of ordinary skill in the art to have used the amounts of menthol, methyl salicylate, thymol and eucalyptol in the composition of the primary reference motivated by the desire to optimize the antiseptic properties of the hinokitiol composition as taught by the secondary reference.

2) Claims 1-19, 21-27 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp in view of Talwar et al. (US 4,945,087).

The primary reference, Lion Corp is discussed above and teaches oral compositions comprising hinokitiol and other essential oils such as menthol. The reference teaches other essential oils may be used in the compositions. The reference differs from the instant claims insofar as it does not teach specifically teach thymol and eucalyptol, and the specific weight percent for methyl salicylate.

Talwar et al. teaches oral compositions comprising thymol and other essential oils. The compositions may be in the form of mouthwashes, toothpaste, liquefied toothbrushing, troches, powders and chewing gums. The compositions comprise thymol, menthol, methyl salicylate and eucalyptol. Thymol is incorporated into the compositions ranging from 0.02 to 0.1% by weight of the composition. The compositions also comprise effective amounts of other essential oils such as eucalyptol, present in amounts of about 0.07 to about 0.11%; menthol, present in amounts of about 0.03% to about 0.06% by weight; and methyl salicylate, present in amounts of about 0.03 to

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about 0.08% by weight based on the total composition. Ethanol and water are also included into the compositions. The reference differs from the instant claims insofar as it does not teach using hinokitiol in the oral compositions.

It would have been obvious to one of ordinary skill in the art to have added the amount of essential oils in the composition of the primary reference motivated by the desire to use amounts that are effective for treatment in the oral cavity as taught by the secondary reference.

Claims 1-19, 21-27 and 31-32 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts Patent Examiner

Art Unit 1614 Leah Roles Frederick Krass
Primary Examiner
Art Unit 1/614